

Remarks

Claims 1-24, 47, 65, 82, 103, 122, 143, 159, 176, 199, and 201-203 were pending. Claims 47, 122, 143, 159, and 201 were previously withdrawn from consideration following election in response to a Restriction Requirement made final by the Examiner. In the instant Amendment, claims 1, 8, 17, 24, 65, 82, 103, 176, and 199 are amended; claims 11-16 are canceled without prejudice; and new claims 204-280 are added. No new matter is introduced.

Prior Office Action

Applicants gratefully acknowledge the Examiner's indication that claims 202 and 203 are allowed. Applicants also gratefully acknowledge the Examiner's express withdrawal of the prior rejection of claims 1-11, 17-18, 20-24, 65, 82, 103, 176, and 199 under 35 U.S.C. § 112, first paragraph, for alleged lack of written description. The Examiner did not comment on the prior rejection of claims 1-11, 17-18, 20-24, 65, 82, 103, 176, 199, and 202-203 under 35 U.S.C. § 112, first paragraph, for alleged lack of enablement, and Applicants therefore presume this rejection has also been withdrawn. The Examiner did not comment on prior rejection of claims 4-7, 20-23, and 103 under 35 U.S.C. § 112, second paragraph, and Applicants therefore presume this rejection has likewise been withdrawn. The Examiner did not comment on previous claim objections, and Applicants therefore presume these objections have also been withdrawn. The Examiner did not comment on previous sequence compliance objections, and Applicants therefore presume these objections have been withdrawn.

Interview Summary

Applicants' representative wishes to thank Examiner Nguyen and his supervisor David Guzza for the telephone interview conducted on December 1, 2003. During the course of the interview, current claim rejections under 35 U.S.C. § 112, first paragraph (enablement), were discussed. It was agreed that the current claim rejections under 35 U.S.C. § 112, first paragraph (enablement), in the office action mailed August 11, 2003, would be overcome if the subject were to be specified to be a mammal and if the minimum length of the oligonucleotide were consistent with the stated features of having poly-G ends and a palindrome inside.

Information Disclosure Statement

During the same telephone interview held on December 1, 2003, Applicants' representative called to the attention of the Examiner that the Information Disclosure Statement (IDS) received by the Patent Office on January 16, 2001, did not appear to have been checked off by the Examiner. The Examiner investigated and, in a follow-up telephone call to Applicants' representative on December 3, 2003, indicated that the IDS has been lost at the Patent Office. In accord with the Examiner's request, Applicants have submitted, under separate cover, a copy of the IDS with Form 1449 and copies of cited references.

New Rejection Under 35 U.S.C. § 112, First Paragraph (enablement)

The Examiner rejected claims 1-18, 20-24, 65, 82, 103, 176, and 199 under 35 U.S.C. § 112, first paragraph, for alleged lack of enablement. More particularly, the Examiner appears to object to the scope of the term "subject" and to the minimum length limitation of "at least 8 nucleotides long" as applied to the immunostimulatory nucleic acids of the invention, comprising a poly-G sequence (at least 3 Gs in a row) at each end and a central palindromic sequence comprising a CpG dinucleotide. For the reasons set forth below, Applicants respectfully request the Examiner to withdraw the rejection of claims 1-18, 20-24, 65, 82, 103, 176, and 199 under 35 U.S.C. § 112, first paragraph, for alleged lack of enablement.

Applicants have amended claims 1, 24, 65, 82, and 103, in accord with the telephone interview of December 1, 2003, to indicate that the subject is a mammalian subject. It is believed that the limitation that the subject be a mammal adequately addresses the Examiner's concerns about the scope of the term "subject".

Furthermore, Applicants have amended claims 1, 17, 24, 65, 82, 103, 176, and 199 to specify that the immunostimulatory nucleic acids of the invention are at least 10 nucleotides long. Support for this amendment can be found, for example, in original claim 17 and at page 25, line 31 – page 32, line 11. A minimum length of 10 nucleotides is consistent with the claim limitations that the immunostimulatory nucleic acids of the invention comprise a poly-G sequence (at least 3 Gs in a row) at each end and a central palindromic sequence comprising a CpG dinucleotide.

Claims 11-16 are canceled without prejudice by this Amendment, rendering moot their rejection under 35 U.S.C. § 112, first paragraph. Applicants thus respectfully request the Examiner to withdraw the rejection of claims 1-18, 20-24, 65, 82, 103, 176, and 199 under 35 U.S.C. § 112, first paragraph (enablement), in view of the claim amendments and cancellations.

New Rejection Under 35 U.S.C. § 112, Second Paragraph

The Examiner rejected claims 8 and 11-16 under 35 U.S.C. § 112, second paragraph, for allegedly failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. More specifically, the Examiner rejected claim 8 as unclear on the basis of the use of the term “modified”. For the reasons set forth below, Applicants respectfully request the Examiner to withdraw the rejection of claims 8 and 11-16 under 35 U.S.C. § 112, second paragraph.

Applicants have amended claim 8 to specify that the immunostimulatory nucleic acid is stabilized. Support for the use of this term can be found, for example, at page 28, line 1, through page 30, line 7.

Claims 11-16 are canceled without prejudice by this Amendment, rendering moot their rejection under 35 U.S.C. § 112, second paragraph.

For the foregoing reasons, Applicants respectfully request the Examiner to withdraw the rejection of claims 8 and 11-16 under 35 U.S.C. § 112, second paragraph.

New Claim Objections

Claim 1 is objected to because of use of the phrase “comprising co-administering an effective amount ...”. Consistent with the suggestion of the Examiner, claim 1 is amended to insert the phrase “to the ... subject” after the term “co-administering”. Accordingly, Applicants respectfully request the Examiner to withdraw the objection to claim 1.

Claim 19 is objected to as being dependent upon a rejected base claim (claim 1). It is believed this objection is overcome in view of the amendment to claim 1. Accordingly, Applicants respectfully request the Examiner to withdraw the objection to claim 19.

New Claims Added

New claims 204 and 205; 222 and 223; 234 and 235; and 250 and 251 are directed to methods in which the coadministering of IFN- α and immunostimulatory nucleic acid is either together or sequential. Support for these claims can be found, for example, at page 45, lines 1-21.

New claims 206-221, all dependent from claim 24, are identical or most closely correspond to original claims 25-33 and 40-46. These claims were previously canceled by preliminary amendment in order to reduce the filing fee.

New claims 224-233, all dependent from claim 65, are identical or most closely correspond to original claims 66-69 and 76-81. These claims were previously canceled by preliminary amendment in order to reduce the filing fee.

New claims 236-249, all dependent from claim 82, are identical or most closely correspond to original claims 83-90 and 97-101. These claims were previously canceled by preliminary amendment in order to reduce the filing fee.

New claims 252-263, all dependent from claim 103, are identical or most closely correspond to original claims 104-109 and 116-121. These claims were previously canceled by preliminary amendment in order to reduce the filing fee.

New claims 264-279, all dependent from claim 176, are identical or most closely correspond to original claims 177-189 and 196-198. These claims were previously canceled by preliminary amendment in order to reduce the filing fee.

New claim 280, dependent from claim 199, is identical or most closely corresponds to original claim 200. This claim was previously canceled by preliminary amendment in order to reduce the filing fee.

Summary

Claims 1, 8, 17, 24, 65, 82, 103, 176, and 199 are amended and claims 11-16 are canceled without prejudice by this Amendment. New claims 204-280 are added, most of which correspond to dependent claims previously canceled by preliminary amendment to reduce the filing fee. A copy of the IDS, Form 1449, and cited references, received by the Patent Office on January 16, 2001, has already been filed under separate cover.

Applicants believe the claims are in condition for allowance. An early and favorable response is earnestly solicited.

Respectfully submitted,



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